UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Milanesi v. C.R. Bard, et al.
Case No. 2:18-cv-1320

MOTIONS *IN LIMINE* ORDER NO. 15

Plaintiff's Motion *in Limine* ("MIL") No. 3 and Defendants' MIL No. 25

Before the Court for consideration is:

(A) MIL No. 3 to Exclude Evidence Relating to the United States Food and Drug Administration (ECF No. 206)[1] filed by Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi, and opposed by Defendants C.R. Bard, Inc. and Davol, Inc (ECF No. 239).

(B) MIL No. 25 to Exclude Evidence Related to the FDA 510(k) Process (ECF No. 188) filed by Defendants Davol, Inc. and C.R. Bard, Inc. and opposed by Plaintiffs (ECF No. 255).

For the reasons that follow, the Court **GRANTS IN PART AND DENIES IN PART** Plaintiffs' Motion and **DENIES** Defendants' Motion.

[1] All docket citations are to the *Milanesi* case, 2:18-cv-1320, unless otherwise noted.

I.[2]

The Milanesi's case will be tried as the second bellwether selected from thousands of cases in this multidistrict litigation ("MDL") titled *In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, 2:18-md-2846. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (Case No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

The Ventralex is a prescription medical device used for umbilical and small ventral hernia repairs. The small and medium sizes were cleared through the 510(k) premarket notification process by the Food and Drug Administration ("FDA") in 2002; the Composix Kugel was listed as a predicate device. The Ventralex Large Hernia Patch used on Mr. Milanesi was cleared via what Defendants call a "no-510(k) rationale line extension" listing the Composix Kugel as the predicate device. (Defs' Memo. in Opp. to Pls' MIL No. 3 at 2, ECF No. 239.)

Plaintiffs bring this action to recover for injuries sustained as a result of the implantation of the Ventralex Large Hernia Patch, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings. After summary judgment, the following claims remain for trial: defective design (strict liability), failure to warn (strict liability), negligence, gross negligence, negligent misrepresentation, fraud and fraudulent misrepresentation, fraudulent concealment, loss of consortium, and punitive

[2] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case *Milanesi v. C.R. Bard*, Case No. 2:18-cv-01320. (ECF No. 167.) All docket citations are to the *Milanesi* case, 2:18-cv-1320, unless otherwise noted.

damages.

The relevant facts here are that Mr. Milanesi underwent surgery to repair what appeared to be a recurrent hernia but was revealed to be a bowel erosion with a fistula and adhesions, which required a bowel resection. Shortly thereafter, Mr. Milanesi suffered a high-grade post-operative small bowel obstruction that required emergency surgery. Mr. Milanesi had the Ventralex Large Hernia Patch implanted ten years earlier to repair a hernia.

In Plaintiffs' MIL No. 3, they move to exclude under Federal Rules of Evidence 402 and 403 all evidence or argument regarding the FDA's "approval" or "clearance" of the Ventralex Large Hernia Patch pursuant to the 510(k) process or any other FDA procedure.

In Defendants' MIL No. 25, they move to Exclude under Rules 42 and 403 to prohibit Plaintiffs from submitting evidence that Bard utilized an inappropriate FDA procedure to bring the Ventralex Large Hernia Patch to market.

II.

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig*., 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and

utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Ind. Ins. Co*., 326 F. Supp. 2d at 846; *see also Koch*, 2 F. Supp. 2d at 1388 ("[A] court is almost always better situated during the actual trial to assess the value and utility of evidence."). The denial, in whole or in part, of a motion *in limine* does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. "Irrelevant evidence is" inadmissible. Fed. R. Evid. 402. A court may exclude relevant evidence under Federal Rule of Evidence 403 "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Evidentiary rulings are made subject to the district court's sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*, 295 F.3d 565, 576 (6th Cir. 2002) ("In reviewing the trial court's decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.").

III.

Both parties agree that a similar issue raised in Plaintiffs' MIL No. 3 was before this Court in the first bellwether case, *Johns v. C. R. Bard, Inc., et al.*, Case No 2:18-cv-01509, where the *Johns* plaintiffs moved to exclude all evidence related to the FDA's 510(k) process because the process is not probative of the safety of the Ventralight ST, or alternatively, the danger of confusing or misleading the jury. The Court granted in part and denied in part the motion, concluding:

> Although the § 510(k) process does not speak to safety, it is nonetheless relevant to this case. The Ventralight ST, a Class II device, was marketed through the § 510(k) process. (ECF No. 231-6 at PageID #12800–01, pp. 14–18.) This is a key piece of the device's history. And as set forth above, federal and state statutes and regulations, among other things, draw the contours of the standard of reasonable care for Defendants in this case. *Downing*, 194 P.3d at 948.
>
> The fact that Ventralight ST received a determination of substantial equivalence in the § 510(k) process is part of Defendants' "story." *Old Chief v. United States*, 519 U.S. 172, 189 (1997).

Johns v. C. R. Bard, Inc., et al., MIL Order No. 4, ECF No. 355 at 15-17.

Plaintiffs here point out that, unlike the Ventralex product at issue in *Johns*, it is undisputed that Defendants did not submit a 510(k) clearance application for the Ventralex Large Hernia Patch that was used on Mr. Milanesi. Thus, Plaintiffs contend that the circumstances surrounding the *Milanesi* case provide additional bases for precluding such evidence and the Court should exclude all or limit the evidence more than was done in *Johns*. This Court agrees.

A. Rule 402

By way of background, the 510(k) review process originates from that the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act ("FDCA") that was enacted in order to "impose[ ] a regime of detailed federal oversight" of medical devices. *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 316 (2008). Under the FDCA, certain devices must complete a

thorough premarket approval ("PMA") process with the FDA before they may be marketed, including all devices that cannot "provide reasonable assurance of the[ir] safety and effectiveness" under less stringent scrutiny, and that are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or "present[ ] a potential unreasonable risk of illness or injury." *Id.* at 317; 21 U.S.C. § 360c(a)(1)(C). The PMA process requires the applicant to demonstrate a "reasonable assurance" that the device is both "safe ... [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 344 (2001); 21 U.S.C. § 360e(d)(2)(A), (B).

In MIL Order No. 4 issued in the context of the *Johns* trial, the Court explained

> [The] FDCA sets forth three categories of medical devices: Classes I, II, and III, with Class III presenting the most risk of injury or illness. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). Class III devices are subject to the "premarket approval" process ("PMA"), which is a "rigorous" and demanding review process. *Id.* However, Class III devices on the market before 1976 are not subject to the PMA ("grandfathered devices") and any class of device may be marketed if the device is "substantially equivalent," 21 U.S.C. § 360e(b)(1)(A), to a grandfathered device or a device that has undergone PMA review. *Id.* at 477–78; *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317, 322 (2008).
>
> The "substantially equivalent" review is "a limited form of review . . . requiring [manufacturers of devices] to submit a 'premarket notification' to the FDA (the process is also known as the '§ 510(k) process,' after the number of the section in the original [FDCA])." *Lohr*, 518 U.S. at 478. The § 510(k) process thus permits the FDA to approve devices for marketing and allows manufacturers to bypass any "further regulatory analysis." *Id.* at 478. Reliance on the § 510(k) process is quite common. *See id.* at 479 ("[T]he § 510(k) premarket notification process became the means by which most new medical devices . . . were approved for the market.").
>
> Crucially, "the § 510(k) process does not comment on safety." *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 574 (6th Cir. 2012). Rather, the § 510(k) process considers "'*equivalence*, not safety,'" which the Supreme Court has determined "provide[s] little protection to the public" because § 510(k) "determinations simply

> compare" the new device with a device approved through the PMA or with a grandfathered device. *Lohr*, 518 U.S. at 493 (quoting *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1348 (11th Cir. 1995), *aff'd in part and rev'd in part*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996))).

Johns v. C. R. Bard, Inc., et al., Motion *in Limine* Opinion and Order No. 4, ECF No. 355 at 15-16.

The Milanesi's argue:

> First, like the Ventralight ST, which was at issue in the *Johns* trial, the Ventralex Large Hernia Patch, as a factual matter, was never "approved" by the FDA through the PMA process.
>
> Unlike the Ventralight ST, however, the Ventralex Large Hernia Patch was not even cleared through the 510(k) process, because Defendants unilaterally determined that a 510(k) application for the Ventralex Large Hernia Patch was not required. While smaller versions of the Ventralex Hernia Patch were previously cleared through the 510(k) process, the predicate device for these applications was the Composite Kugel Mesh, which was subject to a voluntary recall by Bard.
>
> Thus, the relevance of any discussion of the FDA becomes even more attenuated—the Ventralex Large Hernia Patch was not considered by the FDA and further, the recall of the device upon which the design of the Ventralex was premised was a voluntary and not ordered by the Agency.

(Pls' MIL No. 3 at 2, ECF No. 206.)

Plaintiffs conclude that the FDA had little to do with bringing the Ventralex Large Hernia Mesh to market, other than review the 510(k) applications for prior Ventralex devices and the predicate Composix Kugel. As the Court has instructed and detailed in MIL Order No. 4 in the *Johns* trial, FDA clearance of a 510(k) application does not reflect an independent safety evaluation by the Agency. Rather, it is a determination that the device at issue is substantially equivalent to a predicate device – but here, the predicate device itself did not receive an independent evaluation of safety by the FDA.

Defendants respond that in *Johns* the Court admitted FDA evidence with a jury instruction regarding the 510(k) process—allowing Bard to show reasonableness in line with

FDA guidelines. Defendants contend the same should apply here. They reason that, even though the Ventralex Large Hernia Patch was not cleared by FDA, that should not preclude Bard from presenting evidence to the jury that the Ventralex Large Hernia Patch was legally on the market pursuant to FDA guidelines. They argue that "Bard properly followed ***FDA's*** guidelines in deciding which regulatory path to take to market Ventralex large as a line extension on the previously cleared Ventralex small and medium. . . . Keeping this evidence away from the jury is not only unfair to Bard but also does not let the jury hear 'a key piece of the [Ventralex large's] history.'" (Defs' Mem. in Opp. at 2–3) (emphasis in original). As in *Johns*, "the 510(k) process is part of the Defendants' 'story.'" *Id.* (citing *Old Chief v. United States*, 519 U.S. 172, 189 (1997)).

This Court agrees that Defendants should not be precluded from presenting evidence that the Ventralex Large Hernia Patch was legally on the market pursuant to FDA guidelines. Thus, similar to the instruction given in *Johns* related to the 510(k) process, the Court will fashion an instruction on the FDA guidelines related to the introduction of a product through the no-510(k) process. This evidence is relevant.

With regard to the 510(k) process, however, the Court in *Johns* specifically found that it was part of Defendants' "story" because the "Ventralight ST received a determination of substantial equivalence in the 510(k) process." That is not the case here. There is no dispute that Defendants did not submit either a PMA application or a 510(k) clearance application for the Ventralex Large Hernia Patch; the Large Patch did not receive a determination of substantial equivalence in the 510(k) process. Therefore, the Court agrees that the evidence of the 510(k) process is of minimal, if any, relevance.

B. Rule 403

This brings the Court to the second part of the issue, a Rule 403 balance. As to the evidence that the Ventralex Large Hernia Patch was legally on the market pursuant to FDA regulations, the Court finds that the concerns of prejudice and confusion do not substantially outweigh the probative value of the evidence.

As to the 403 balance related to 510(k) evidence, the Court in *Johns* explained:

> Plaintiff has concerns about "inevitable mini-trials" addressing the meaning of the § 510(k) process and the risk of confusing or misleading the jury. (ECF No. 231 at PageID #12636.) The Court shall instruct the jury on the § 510(k) process and explain that the § 510(k) process does not mean that the FDA vouches for the safety of the device or that the FDA conducts any independent testing on the device. No experts will be permitted to opine on the background or legal meaning of the process.
>
> This course sufficiently addresses Plaintiff's Rule 403 concerns. As other courts have noted, exclusion of any evidence about the § 510(k) process also risks confusing the jury because "[m]any of the relevant events in this case occurred in the context of FDA § 510(k) review, and much of the evidence is best understood in that context." *In re Bard IVC Filters Prods. Liab. Litig.*, 289 F. Supp. 3d 1045, 1049 (D. Ariz. 2018). Indeed, jurors "who hear a story . . . may be puzzled at the missing chapters." *Old Chief*, 519 U.S. at 189 (interpreting the scope of Rule 403). Such is the case here when mention of the FDA is inevitable and a juror may wonder why the Ventralight ST was permitted to be marketed in the first place. On balance, the lesser risk is permitting the jury to hear this evidence, guided by an accurate explanation of the § 510(k) process from the Court.

Johns v. C. R. Bard, Inc., Motion *in Limine* Opinion and Order No. 4, ECF No. 355 at 16-17.

The *Milanesi* Plaintiffs argue that these concerns addressed in *Johns* are not meaningful here. That is, since the Ventralex Large Hernia Patch did not proceed through the 510(k) process there is a stronger risk of confusing or misleading the jury and wasting judicial resources and the jury's time because it would require the parties to engage in a time-consuming mini-trials. This Court agrees.

Plaintiffs posit that "[i]n the *Johns* trial, to minimize any juror confusion and the risk of

the jury applying undue weight to evidence pertaining to FDA 510(k) clearance of the Ventralight ST, the Court provided an instruction to the jury regarding the approval and clearance process for medical devices and sought to exclude testimony and opinion relating to FDA regulations and interpretations of the law." (Pls' MIL No. 3 at 5, ECF No. 206.) Defendants assert that a similar instruction will suffice here.

Plaintiffs point out, however, that despite the Court's instructions, numerous and unnecessary delays occurred, as the Court repeatedly addressed objections at sidebar and either struck testimony or gave additional instructions to the jury. Plaintiffs provide the following examples:

> DR. TILLMAN: So while there is a specific section that's called a warning section, I also believe that the intent of this adverse reaction section is to inform physicians and patients, where appropriate, that these are things that can happen –
>
> THE COURT: Let me stop you right there. The intent part is stricken.

Aug. 31, 2021 Trial Tr., Vol. 17 at 20:22-21:2 [PAGEID No. 31217-18] (testifying about the content of the Ventralight ST IFU).

> MR. BROWN: What's the resorbs from the site within 30 days, what's the significance of that?
>
> DR. TILLMAN: So I think one of the reasons this is significant is the way the FDA evaluate materials.
>
> THE COURT: Again, the witness can't speak for the FDA. Rephrase, if you would.

Id. at 25:13-18 [PAGEID No. 31222].

> DR. RENTON: The SAGES project that's mentioned here, because of federal regulations, it's very limited what they could put on the box that the mesh comes in and we wanted some more –
>
> MR. O'BRIEN: Your Honor –
>
> . . . .

> THE COURT: But if you ask him what information is there, that's fine. If you ask him to comment on federal regulations, that's not fine. So I know he said that, not in response to your question. I'm going to strike the answer, and you can go ahead and start that over again. All right.

Aug. 25, 2021 Trial Tr., Vol. 15 at 66:25-67:20 (PAGEID No. 30708-09] (testifying about information contained on the labeling).

> DR. TILLMAN: So I think it's important to recognize that when FDA clears a device, they're not just clearing the technology, they're clearing it for a specific indication. And so the purpose here is to make sure that the person using this device knows what it's been cleared for because that's -- those are the uses for which we have -- we have scientific evidence demonstrating the device should demonstrate a reasonable degree of safety and effectiveness.
>
> MR. O'BRIEN: Your Honor, I'm sorry. I need to approach on this.
>
> THE COURT: I'll see you at sidebar. (The following proceeding was held at sidebar.)
>
> THE COURT: Mr. O'Brien.
>
> MR. O'BRIEN: So this violates the ruling on that this 510(k) process is about safety. I think that I hate to do it, but I'm going to ask you to read the instruction again or either strike the testimony or read the instruction again.

Aug. 26, 2021 Trial Tr., Vol. 16 at 254:6-255:23 [PAGEID No. 31165-66].

The Court later gave the following instruction:

> THE COURT: Members of the jury, I want to go back and remind you. I know that the witness knows this. But the 510(k) process we've discussed in some detail and you've heard lots of testimony about it. It is an authorization but it's not a decision by the FDA about a particular product being safe and effective. You've heard that already. The different classifications bring about different levels of review. So it is an authorized authorization to bring it to market but it's not the same as if it went through the full review. I just want to clear that up.

Id.

It is evident that the Court addressed repeated objections at sidebar or the Court was required to strike testimony or provide instructions to the jury. In the *Milanesi* case, where the

product at issue did not undergo the 510(k) process, the potential for juror confusion is increased significantly from a product like the one used by Mr. Johns that did undergo the 510(k) process.

And, where witnesses cannot provide testimony about what the FDA intends or believes, the jury may easily be misled. Given the lack of relevance of the 510(k) testimony to the ultimate questions that the jury must decide, the required time to present the evidence and the potential prejudice far outweigh the probative value of such testimony. Instead the Court will instruct the jury on the FDA process and regulatory scheme, similar to what occurred in *Johns*, but including the fact that the 510(k) was not utilized.

IV.

Defendants' MIL No. 25 relates to the FDA procedure by which they brought the Ventralex Large Hernia Patch to market. The parties do not dispute that there were three pathways by which the product could be taken to market: PMA, 510(k), no-510(k). Defendants used the third way, contending:

> The regulatory process for making modifications to the Ventralex *required Bard to determine* over time whether changes to the manufacturing process and introduction of a modified design raised significant questions of safety and effectiveness not answered by the previous 510(k) clearance by FDA.
>
> If, after review, *a company decides* there are no new significant safety and effectiveness issues, or changes to the intended use, then no new 510(k) notification is needed prior to introduction of the modified product. *See* Dispositive Motions Order No. 3, ECF No. 167 ("A no-510(k) rationale is when a 510(k) application does not need to be submitted because the manufacturer has made changes that do not significantly affect the safety or effectiveness of the device.") (citation omitted).

(Defs' MIL No. 25 at 4, ECF No. 188) (emphasis added).

Defendants maintain that Bard was in compliance with the FDA no-510(k) process, stating:

> This process is clearly outlined in the FDA January 10, 1997, *Guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device."* Exhibit

> 3 ("1997 FDA Guidance"). The 1997 FDA Guidance explains that FDA *relies on the manufacturer to consider whether or not a 510(k) premarket notification is warranted*.
>
> It highlights the availability of a no-510(k) rationale for a simple line extension, like an additional size, that does not have a significant impact on the safety or efficacy of the device. *See id*. at 30 (outlining three questions manufacturer's should address in considering whether a new 510(k) is necessary when making change to "dimensional specifications," including "Affect indications for use?," Are clinical data necessary to establish [safety and effectiveness]. . . ?," and "Do results of design validation raise new issues of [safety and effectiveness]?").

Id. (emphasis added).

Defendants further contend that Bard's appropriate and correct answers to these questions presented in the 1997 FDA Guidance led to its decision to utilize the no-510(k) process, which was the appropriate and correct regulatory pathway to bring to market the Ventralex Large Hernia Patch. Defendants contend:

> Indeed, as Davol's former Vice President of Regulatory Affairs, Stephanie Baker, testified, Bard followed FDA guidance in bringing the Ventralex large to market, FDA never raised any concerns regarding the product's regulatory pathway, and the device was appropriately on the market in 2007 at the time of Mr. Milanesi's implant."
> . . . .
>
> As Ms. Baker testified, the Ventralex large was appropriately on the market in the United States according to FDA regulatory standards as of the time of Mr. Milanesi's July 2007 implant. Baker Dep. at 382:24-383:5, 384:2-9. While it has been informed of the no-510(k) rationale for the Ventralex large in subsequent interactions, the FDA has not raised any issues "around the route to market" for the device. *Id*. at 406:8-17, 441:24-442:24.

(Defs' MIL 25 at 3, 5, ECF No. 188) (citing Exhibit 1, Dep. of Stephanie Baker, Jan. 22, 2020, ("Baker Dep.") at 382:24-383:5, 384:2-9, 405:16-406:17; 441:21-442:24).

This Court in its decision above related to Plaintiffs' MIL No. 3 permitted Defendants to offer this evidence. Yet, in MIL No. 25, Defendants ask this Court to preclude Plaintiffs from discussing Bard's choice to utilize the no-510(k) route to market instead of a 510(k) or a PMA

clearance, arguing:

> Bard expects Plaintiffs to suggest that because the Ventralex large came to market as part of the FDA's approved "no-510(k) rationale" process, it was not technically "cleared" by the FDA for marketing, implying that the product was not legally on the market. Just the opposite, however, is true.
>
> Bard properly followed FDA's guidelines in deciding which regulatory path to take to market Ventralex large as a line extension on the previously cleared Ventralex device, and there is no evidence that FDA has challenged that the device was legally on the market.

(Defs' Mot. at 1, ECF No. 188.)

Plaintiffs respond:

> To be clear, Plaintiffs have no intention of arguing that the Ventralex Large Patch was on the market *illegally*, as Defendants suggest. However, Plaintiffs should be able to introduce evidence that the FDA did not "clear" the device and that it was released to market without its knowledge, or without the knowledge of Bard's safety concerns at that time. Further, Plaintiffs' experts should be permitted to opine that the unilateral decision by Bard *not to submit a 510(k)* application, was inappropriate in light of the knowledge Bard had at that time

(Pls' Mem. in Opp. at 1, ECF No. 255.)

This Court agrees. This evidence is relevant to Defendants' story, as explained above in this Court's discussion of Plaintiffs' MIL No. 3, and Plaintiffs cannot be prohibited from responding to this evidence. For example, Plaintiffs disagree with Defendants' assessment of the evidence they cited about Bard following the 1997 FDA Guidelines:

> Defendants are correct to cite a 1997 FDA Guidance Document, *Deciding When to Submit a 510(k) for a Change to an Existing Device,* which while not legally binding on a manufacturer, contains the FDA's recommendations. *See* Defs' MIL No. 25 at Ex. 3. As noted by Defendants, "the FDA relies on the manufacturer to consider whether or not a 510(k) premarket notification is warranted." *Id*. at 4. In doing so, the FDA suggests three questions the manufacturer should answer for itself when making a change to dimensional specification, two of which are pertinent here:
>
> • Are clinical data necessary to establish safety and effectiveness?

> • Do results of design validation raise new issues of safety and effectiveness?
>
> As the Agency is relying on the manufacturers making these determinations and is not reviewing a 510(k) clearance application at all, it is the *manufacturer's* decision-making that is in question here—not the FDA processes or FDA's conclusions. Thus, Plaintiffs should be permitted to introduce evidence and opinion that Bard had information indicating the answer to both questions above was "Yes," and that it should have disclosed its information and concerns to the Agency in a 510(k) application.

(Pls' Mem. in Opp. to Defs' MIL No. 25 at 2–3, ECF No. 255.)

Additionally, the Court is not persuaded by Defendants' position that this evidence should be excluded under the reasoning utilized in *Johns* for a similar issue. They argue:

> An analogous issue arose in *Johns*, wherein this Court ruled that evidence and argument regarding any alternative regulatory pathway—*i.e.*, the Premarket Approval process versus the 510(k) clearance process through which the Ventralight ST reached the market—was excluded. *See Johns v. C. R. Bard, Inc.*, *et al.*, Motions *In Limine* Order No. 3, ECF No. 332 at 2 ("Plaintiff may not present evidence or argument regarding Bard's ability to obtain a Premarket Approval[.]"); *see also Johns v. C. R. Bard, Inc.*, *et al.*, September 10, 2020, Hearing Tr., ECF No. 345 at 56:2-3 ("So there's not going to be any reference to the other process. That's out.").
>
> Here, the need for a similar order precluding any suggestion, inference, evidence or argument that the Ventralex large was not legally on the market in the United States is equally important, if not more so, given that Plaintiffs have already signaled their intent to portray Bard's use of the no-510(k) rationale process as somehow sinister or untoward.

(Defs' MIL No. 25 at 1–2, ECF No. 188.)

First, Plaintiffs are not presenting evidence that the Ventralex Large Hernia Patch was illegally on the market. Instead, they are simply disagreeing with Defendants that Bard utilized the appropriate route to market. In *Johns*, the consideration was different. There, the Court prohibited argument or evidence that Bard should have pursued a PMA for the Ventralight ST because the Court had determined that pathway was intended for Class III devices and the Ventralight ST was not a Class III device.

Finally, any concern of prejudice under Rule 403 is alleviated by the Court's instruction that it will fashion as discussed above. That is, in denying Plaintiffs' request to prohibit Defendants from presenting its no-510(k) rationale evidence, the Court indicated that it would issue a limiting instruction to avoid jury confusion or prejudice.

V.

For the reasons set forth above, the Court **GRANTS IN PART AND DENIES IN PART** Plaintiffs' MIL No. 3, (ECF No. 206) and **DENIES** Defendants' MIL No. 25 (ECF No. 188). Specifically, the Court finds:

1. The evidence of the 510(k) process is of limited, if any, relevance, but even if it were relevant, it is excluded under Rule 403. Thus, evidence related to the FDA's "approval" or "clearance" of the Ventralex Large Hernia Patch pursuant to the 510(k) process or any explanations of the 510(k) process in this vein is excluded.

2. Defendants' and Plaintiffs' testimony regarding Bard's decision to pursue the non-510(k) route for the Ventralex Large Hernia Patch is relevant and it is not excluded under Rule 403. Therefore, evidence of the decision making undertaken by Defendants to bring the Ventralex Large Hernia Patch to market is not excluded.

The Court shall fashion a limiting instruction on this FDA issue/process similar to the one it utilized in *Johns* for the 510(k) evidence. As with all *in limine* decisions, this ruling is subject to modification should the facts or circumstances at trial differ from that which has been presented in the pre-trial motion and memoranda.

IT IS SO ORDERED.

11/30/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE